

Amendments to the Drawing

The Examiner has requested illustration of the motion control apparatus of claim 14. Accordingly please accept the replacement sheet. The requested motion control apparatus and associated reference numeral 340 has been added to Figure 1A.

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed January 7, 2008. Currently, claims 1-48 remain pending of which claims 12, 23, 24, and 28-48 are withdrawn from consideration. Claims 1-11, 13-22, and 25-27 have been rejected. Although not noted in the Office Action Summary, claims 2 and 26 have been objected to. Favorable consideration of the following remarks is respectfully requested.

Elections/Restrictions

As an initial matter, Applicants note that the Examiner does not agree that the elements of claims 23, 24, and 29 belong to elected Species A (Fig. 1A) and D (Fig. 2A-2D). The Examiner's attention is directed to the description of the embodiment of Figure 1A found at page 3, lines 11-13 where the configuration of the distal device is as follows: "Distal device 304 may have an arcuate shape, or may be formed into a *loop*, coil, paddle, whisk, *zigzag*, helical or other shape suitable for fragmenting an embolus." The Examiner will appreciate that only one configuration of distal device 304 could have been illustrated in the single Figure 1A. Alternate configurations were selected for illustration of the distal device in Fig. 1B and Fig. 1C and for description in claims 23 and 24, however either of those, or other, distal device configurations could have been provided in Figure 1A.

Applicants further note that the Examiner has particularly commented on claim 29, said to be illustrated in Fig. 1B, which differs from Fig. 1A in that the distal end of catheter 402 is not angled at the approximately 90° angle of catheter 302. The angle of the distal end in Fig. 1A is not specified to be a right angle although the illustrated angle is closer to a 90° angle than is that of Fig. 1B. It is felt that a difference of as little a degree in the angle between the embodiments of Figure 1A, Species A, and Figure 1B, Species B, although technically distinguishable, is insufficient to define a separate species. As noted above, the choice of a *loop* from the partial list of possible configurations for the distal end of device 304 for illustration in Figure 1B is consistent with the lack of a need to further identify the corresponding element in Figures 1B and 1C since they are specifically to be found in the description of the possible configurations

of a distal device end provided for Figure 1A. The device of claim 29 is searchable within the same classification as the elected claims, as noted by the Examiner in the restriction requirement of September 28, 2007, and so should not impose an undue burden upon the Office. Reconsideration of the further restriction requirement is respectfully requested.

Claim Objections

Claim 2 was objected to because of the informality, “unclogged”. The claim has been amended as suggested by the Examiner.

Claim 26 was objected to as being of improper dependent form in that it was said to fail to further limit the subject matter of an earlier claim. The Examiner’s attention is drawn to claim 25, from which claim 26 depends. Claim 25 provides for a total displacement of 120 mm of which 20 mm is proximal and 100 mm is distal. Claim 26 limits the range of total displacement to 17 mm of which 2 mm is proximal and 15 mm is distal. Accordingly, claim 26 further limits the total range of motion, the proximal extent of motion, and the distal extent of motion provided by claim 25. Applicants respectfully request reconsideration and withdrawal of the objection.

Claim Rejections – 35 USC § 102

Claims 1-5, 8-11, and 13 stand rejected under 35 USC §102(b) as anticipated by Dubrul et al. (U.S. Published Patent Application No. 2002/0019597), hereinafter Dubrul. After careful review, Applicant must respectfully traverse this rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Additionally, “[t]he identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (MPEP § 2131). Accordingly, Dubrul et al. must

teach each and every element in as complete detail as is contained in claims 1-5, 8-11, and 13, as is required for anticipation.

Applicant respectfully asserts that Dubrul et al. fails to teach each and every element of claim 1-5, 8-11, and 13. Nowhere does Dubrul appear to teach, “a vibratable wire for changing the shape of an embolus at least partially disposed within the lumen of the second elongate shaft”, as recited in claim 1.

Instead, Dubrul appears to disclose, in the embodiment of Figs. 9A, 11C, 11F, and 11G, cited by the Examiner, a tissue cutter adapted for piercing the body and cutting a body of tissue free from the surrounding mass. The cutter comprises, as presented in Figures 11C-11G, a first outer shaft 146 and a second inner shaft 134. The Examiner asserts that the wire of the mesh cutter (112 or supposedly 138) found in Figures 9A and 11F provides the vibratable wire. Mesh cutter 112 of Figure 9A is deployed from between inner tube 115 and outer tube 117 and so does not appear to be available to change the shape of an embolus within the lumen of inner tube 115. No embolus appears to be identified in the specification of Dubrul. To the extent that the cutter of Dubrul deals with a mass of tissue, the tissue would appear to remain in substantially the same shape in which it is excised from the surrounding tissue and any change in shape appears to be the result of preliminary fluid removal prior to the cutting step rather than the action of a wire. As shown in the sequence of Figs. 9, the mesh tissue cutter 112 of Fig. 9A appears to both cut (along edge 114) and simultaneously surround tissue 100 cut from surrounding tissue 18. If cutter 112 is the wire, there appears to be no lumen of a second elongate shaft and if cutter 112 is to provide the second shaft having “a distal opening, the tip movable between a first state and a second state wherein the distal opening has a greater cross-sectional area in the second state than in the first state, there would appear to be no “vibratable wire for changing the shape of an embolus at least partially disposed within the lumen of the second elongate shaft”. In either interpretation, at least one element of the pending claim 1 appears to be missing.

In the alternative embodiment of Fig. 11C and/or 11F, the Examiner asserts that “second elongate shaft (tubular wire mesh tissue cutter 138 with tubular mesh 144 in Fig. 11F or 112 Fig. 9A.)” is present and resides at least partially within the lumen of the first elongate shaft. It should be noted that “wire tissue cutter 138” of Figure 11C is a separate

element having a separate function from that of “tubular mesh material 144” and that 138 and 144 are deployed at different stages of the tissue cutting procedure. Although wire tissue cutter 138 is characterized by the Examiner as a tubular mesh material, it is depicted as a single wire attached distally to the *outside* of inner tube 134 in Figs 11D and 11E and apparently is present in Figures 11C and 11F in that form although it is not identified as such.

Further, there does not appear to be a “a tip disposed on the distal end of the second shaft having a cavity fluidly connected to the lumen of the second shaft and a distal opening, the tip movable between a first state and a second state wherein the distal opening has a greater cross-sectional area in the second state than in the first state” in Dubrul. It is unclear how wire 138 could have either a cavity fluidly connected to a lumen of the wire 138, or be a second shaft having a “tip moveable between a first state and a second state wherein the distal opening has a greater cross-sectional area in the second state than in the first state”. The tip of the distal end of the second shaft 134 of Dubrul appears to be of fixed diameter in each of the cited Figures 11C-11G. Wire 138 appears to be different in form and location, as well as function, from the vibratable wire of pending claim 1. Wire 138 appears to be deployed *after* any “occasional particles”, which might arguably correspond to emboli even though they are not disposed within a blood vessel as required by the definition of emboli, have been withdrawn by the apparatus of Figure 11A. Wire 138 is an arc attached at its distal end in a manner which would prevent it from changing the shape of an embolus within the lumen of the second elongate shaft 134, and its purpose appears to be to cut surrounding healthy tissue from the larger body. In the absence of “a vibratable wire for changing the shape of an embolus at least partially disposed within the lumen of the second elongate shaft” or “a tip disposed on the distal end of the second shaft having a cavity fluidly connected to the lumen of the second shaft and a distal opening, the tip movable between a first state and a second state wherein the distal opening has a greater cross-sectional area in the second state than in the first state” Dubrul would appear to fail to anticipate claim 1 and Applicants respectfully request that the rejection be withdrawn

Additionally, for similar reasons, as well as others, claims 2-5, 8-11, and 13, which depend from claim 1 and include significant additional limitations, are believed to

be not anticipated by Dubrul et al. and Applicant respectfully requests withdrawal of the rejections.

Claims 1-5, 7-8, 11, and 13 stand rejected under 35 USC §102(b) as anticipated by White (WO 01/97697). After careful review, Applicant must respectfully traverse this rejection.

Applicant respectfully asserts that White fails to teach each and every element of claim 1-5, 7-8, 11, and 13. Nowhere does White appear to teach “a vibratable wire for changing the shape of an embolus at least partially disposed within the lumen of the second elongate shaft”, as recited in claim 1.

Instead, White appears to disclose, in the embodiment of Figs. 1 and 5a as well as the text at page 20, lines 1-20, a guidewire 11 bearing a capture means or filter 10 which expands distally beyond the thrombus 22, a generalized thrombectomy means 30, and an extractor the distal end of which expands to accommodate the thrombus, the thrombectomy means and the capture means or filter in their expanded states as shown in Figure 5b. Although White appears to contemplate the use of the device of Figs. 1 and 5a for the removal of an embolus, the description of the operation of the device is directed to the removal of a thrombus from a vessel wall by scraping and the thrombus is generally not illustrated. The only emboli which are illustrated and discussed appear to be found in Fig. 5b as elements 102 which are much smaller than the capture device and do not appear to be altered in shape by either the guidewire or the capture device.

Further there appears to be no disclosure within White which indicates that the guidewire 11 either vibrates or otherwise interacts with the thrombus of Fig. 1 in any way. It will be seen that it is within catheter 23 which prevents contact between the guidewire and the thrombus. The thrombus is not shown in Fig. 5a and so its interaction with the guidewire cannot be judged directly, however in Fig. 5b, the equivalent thrombus contacts only catheter 23 and the thrombectomy device 30 and not guidewire 11. The passage at page 20, lines 1-20 is said by the Examiner to disclose the “vibratable wire (guidewire, 11, Fig. 5a) for changing the shape of an embolus at least partially disposed within the lumen of the second elongate shaft”. Within that text, the guidewire appears only in its usual role in which various devices are introduced along it. Embolus

does not appear and the root appears only in the formation “thromboembolism”. The only potential interaction between the thrombus and the guidewire appears as “(b) introducing a guidewire 11 through the lumen of the percutaneous sheath 21 into the lumen of the vessel 39, so that it extends distally beyond the thrombus 22” which does not appear to rise to the standard of disclosing “a vibratable wire for changing the shape of an embolus” and the proposed interaction, if any, appears to take place well beyond the lumen of the second shaft identified as shaft 17 by the Examiner. For at least these and other reasons, White does not appear to anticipate the invention of claim 1 and Applicants respectfully request that the rejection be withdrawn.

Additionally, for similar reasons, as well as others, claims 2-5, 7-8, 11, and 13, which depend from claim 1 and include significant additional limitations, are believed to be not anticipated by White and Applicants respectfully request withdrawal of the rejections.

Claims 14-15 and 18-21 stand rejected under 35 USC §102(b) as anticipated by Uflacker (U.S. Patent No. 5,243,997). After careful review, Applicant must respectfully traverse this rejection.

Applicant respectfully asserts that Uflacker fails to teach each and every element of claim 14-15 and 18-21. Nowhere does Uflacker appear to teach “a motion control means connected to the proximal end of the wire configured to produce a motion at the distal end of the wire which changes the shape of an embolus with which the distal end is in contact”, as recited in amended claim 14.

Instead, Uflacker appears to disclose a “vibrating device (which) permits the guide wire to be more easily passed *through* a stenotic segment of a blood vessel”. Having easily passed through the stenotic segment, the distal end of the guidewire of is no longer positioned to change the shape of the stenosis under the influence of the motion control means. Although the Examiner asserts that “the catheter further comprises a device (inductive element 84, Fig. 4) attached to the distal end of the wire for changing the shape of an embolus” in discussing claim 19, there does not appear to be an embolus disclosed anywhere within Uflacker and so Uflacker cannot be said to anticipate each and every element as set forth in claim 14. The Examiner’s attention is drawn to the only

appearance of “inductive” found within Uflacker at col. 5, line 43 where it appears in the discussion of an external charging circuit for the vibratory device as illustrated in Fig. 7. Element 84 of Fig. 4 is identified only as the tip of guide wire 12 in what appears to be an erroneous reuse of the reference numeral within the Figures.

In discussing pending claim 20, the Examiner asserts that the device is “configured to change the shape of the embolus to unclog a distal catheter lumen (since the inductive element is attached to the distal end of the guide wire, it must be able to unclog a distal catheter lumen in order to get through (the) catheter into the blood vessel.” As noted before, the inductive element 84 is *external* to the body and not within the blood vessel. In addition, Applicants respectfully call the Examiner’s attention to the lack of a clog or other obstruction within the lumen of the catheter as disclosed by Uflacker, much less the presence of an embolus. Uflacker cannot disclose unclogging a lumen which is not clogged.

In discussing claim 21, the Examiner speculates that were the inductive element of Uflacker to hit an embolus not found within Uflacker, it “can hit and fragment an embolus when the vibrating device vibrates the guide wire, Fig. 4.” As above, neither the specification nor Fig. 4 discloses an embolus and nothing in Uflacker appears to indicate that hitting an embolus with the external inductive element of Uflacker could fragment or otherwise change the shape of the purported embolus were it to be present. In view of the above, Uflacker appears to not disclose each and every element as set forth in claim 14 and Applicants respectfully request that the rejection be withdrawn.

Additionally, for similar reasons, as well as others, claims 15 and 18-21, which depend from claim 14 and include significant additional limitations, are believed to be not anticipated by White and Applicants respectfully request withdrawal of the rejections.

Claim Rejections – 35 USC § 103

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul et al. (U.S. Published Patent Application No. 2002/0019597) in view of Kurz et al. (U.S. Patent No. 6,692,504). After careful review, Applicant must respectfully traverse this rejection.

In discussing Dubrul in this context, the Examiner asserts that “Dubrul et al. and Kurz et al. are analogous art because they are from the same field of endeavor. Applicants respectfully disagree and note that Dubrul et al. is from U.S. Class 600/567, (Body pierced by tubular cutter or rod-type punch), and Kurz et al. is from U. S. Class 606/127, (Means for concretion removal - extracting or easing the natural passage of a calculus or “stone”) or alternatively, 606/110 (Means for removing tonsils, adenoids or polyps) or 604/106 (Expanding arm or finger) while the pending application is classified in U. S. Class 606/200 (Internal pressure applicator (e.g., dilator), with emboli trap or filter). Body piercing by tubular cutters and extracting or easing the passage of stones do not appear to be structurally related to each other, much less to the reshaping and removal of a soft embolus from within vasculature.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed previously, nowhere does Dubrul et al. appear to disclose “a vibratable wire for changing the shape of an embolus at least partially disposed within the lumen of the second elongate shaft” as found in claim 1. Nowhere does Kurz et al. appear to remedy the shortcomings of Dubrul et al. Therefore, Dubrul et al. in view of Kurz et al. does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

Additionally, for similar reasons, as well as others, claim 6, which depends from claim 1 and includes significant additional limitations, is believed to be patentable over Dubrul et al. in view of Kurtz et al. and Applicant respectfully requests withdrawal of the rejection.

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over White (WO 01/97697) in view of Kurz et al. (U.S. Patent No. 6,692,504). After careful review, Applicant must respectfully traverse this rejection.

As discussed previously, nowhere does White appear to disclose “a vibratable wire for changing the shape of an embolus at least partially disposed within the lumen of the second elongate shaft” as found in claim 1. Nowhere does Kurz et al. appear to

remedy the shortcomings of White. Therefore, White et al. in view of Kurz et al. does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

Additionally, for similar reasons, as well as others, claim 6, which depends from claim 1 and includes significant additional limitations, is believed to be patentable over White in view of Kurtz et al. and Applicant respectfully requests withdrawal of the rejection.

Claims 9 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over White (WO 01/97697) in view of Dubrul et al. (U.S. Published Patent Application No. 2002/0019597). After careful review, Applicant must respectfully traverse this rejection.

As discussed previously, nowhere do either White or Dubrul et al. appear to disclose “a vibratable wire for changing the shape of an embolus at least partially disposed within the lumen of the second elongate shaft” as found in claim 1. Nowhere does Dubrul et al. appear to remedy the shortcomings of White. Therefore, White et al. in view of Dubrul et al. does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

Additionally, for similar reasons, as well as others, claims 9 and 10, which depend from claim 1 and include significant additional limitations, are believed to be patentable over White in view of Dubrul et al. and Applicant respectfully requests withdrawal of the rejection.

Claims 16 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Uflacker (U.S. Patent No. 5,243,997) in view of Dubrul et al. (U.S. Patent No. 5,380,273). After careful review, Applicant must respectfully traverse this rejection.

As discussed previously, nowhere does Uflacker appear to disclose “a motion control means connected to the proximal end of the wire configured to produce a motion at the distal end of the wire which changes the shape of an embolus with which the distal end is in contact” as found in claim 14. Nowhere does Dubrul et al. appear to remedy the shortcomings of Uflacker. Therefore, Uflacker in view of Dubrul et al. does not appear

to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

Additionally, for similar reasons, as well as others, claims 16 and 17, which depend from claim 14 and include significant additional limitations, are believed to be patentable over Uflacker in view of Dubrul et al. and Applicant respectfully requests withdrawal of the rejection.

Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Uflacker (U.S. Patent No. 5,243,997) in view of White (WO 01/97697). After careful review, Applicant must respectfully traverse this rejection.

As discussed previously, nowhere does Uflacker appear to disclose “a motion control means connected to the proximal end of the wire configured to produce a motion at the distal end of the wire which changes the shape of an embolus with which the distal end is in contact” as found in claim 14. Nowhere does White appear to remedy the shortcomings of Uflacker. Therefore, Uflacker in view of White does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

Additionally, for similar reasons, as well as others, claim 22, which depends from claim 14 and includes significant additional limitations, is believed to be patentable over Uflacker in view of White and Applicant respectfully requests withdrawal of the rejection.

Claim 26 was rejected under 35 U.S.C. 103(a) as being unpatentable over Uflacker (U.S. Patent No. 5,243,997) in view of Bates et al. (U.S. Patent No. 6,224,612). After careful review, Applicant must respectfully traverse this rejection.

As discussed previously, nowhere does Uflacker appear to disclose “a motion control means connected to the proximal end of the wire configured to produce a motion at the distal end of the wire which changes the shape of an embolus with which the distal end is in contact” as found in claim 14. Nowhere does Bates appear to remedy the shortcomings of Uflacker. Therefore, Uflacker in view of Bates does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

Additionally, for similar reasons, as well as others, claim 26, which depends from claim 14 and includes significant additional limitations, is believed to be patentable over Uflacker in view of Bates and Applicant respectfully requests withdrawal of the rejection.

Claim 26 was rejected under 35 U.S.C. 103(a) as being unpatentable over Uflacker (U.S. Patent No. 5,243,997) in view of Briskin (U.S. Patent No. 5,728,062). After careful review, Applicant must respectfully traverse this rejection.

As discussed previously, nowhere does Uflacker appear to disclose “a motion control means connected to the proximal end of the wire configured to produce a motion at the distal end of the wire which changes the shape of an embolus with which the distal end is in contact” as found in claim 14. Nowhere does Briskin appear to remedy the shortcomings of Uflacker. Therefore, Uflacker in view of Briskin does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

Additionally, for similar reasons, as well as others, claim 26, which depends from claim 14 and includes significant additional limitations, is believed to be patentable over Uflacker in view of Briskin and Applicant respectfully requests withdrawal of the rejection.

Claim 26 was rejected under 35 U.S.C. 103(a) as being unpatentable over Uflacker (U.S. Patent No. 5,243,997) in view of Graves et al. (U.S. Patent No. 5,522,819). After careful review, Applicant must respectfully traverse this rejection.

As discussed previously, nowhere does Uflacker appear to disclose “a motion control means connected to the proximal end of the wire configured to produce a motion at the distal end of the wire which changes the shape of an embolus with which the distal end is in contact” as found in claim 14. Nowhere does Graves appear to remedy the shortcomings of Uflacker. Therefore, Uflacker in view of Graves does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

Additionally, for similar reasons, as well as others, claim 26, which depends from claim 14 and includes significant additional limitations, is believed to be patentable over Uflacker in view of Graves and Applicant respectfully requests withdrawal of the rejection.

Claim 27 was rejected under 35 U.S.C. 103(a) as being unpatentable over Uflacker (U.S. Patent No. 5,243,997) in view of Wilk et al. (U.S. Patent No. 5,417,697). After careful review, Applicant must respectfully traverse this rejection.

As discussed previously, nowhere does Uflacker appear to disclose “a motion control means connected to the proximal end of the wire configured to produce a motion at the distal end of the wire which changes the shape of an embolus with which the distal end is in contact” as found in claim 14. Nowhere does Wilk et al. appear to remedy the shortcomings of Uflacker. Therefore, Uflacker in view of Wilk et al. does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

Additionally, for similar reasons, as well as others, claim 27, which depends from claim 14 and includes significant additional limitations, is believed to be patentable over Uflacker in view of Wilk et al. and Applicant respectfully requests withdrawal of the rejection.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: April 4, 2008

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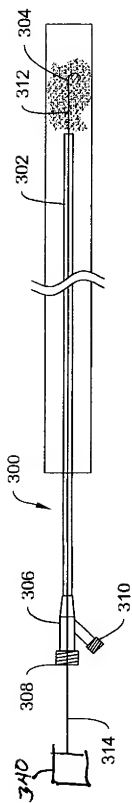


Fig. 1A

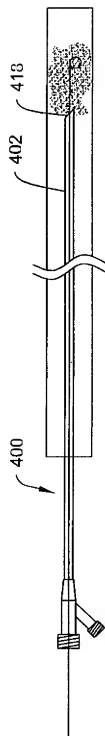


Fig. 1B

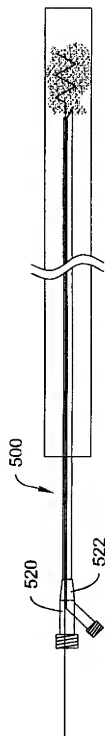


Fig. 1C